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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,161	03/22/2001	M. Cynthia Goh	13626	2783
293	7590	02/09/2005	EXAMINER	
Ralph A. Dowell of DOWELL & DOWELL P.C. 2111 Eisenhower Ave. Suite 406 Alexandria, VA 22314			YANG, NELSON C	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,161

Applicant(s)

GOH ET AL.

Examiner

Nelson Yang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 34-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 14-33 and 66-70 is/are rejected.
- 7) ☒ Claim(s) 1-13 and 34-65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 14 is acknowledged and has been entered.
2. Applicant's addition of claims 67-70 is acknowledged and has been entered.
3. Claims 14-33, 66-70 are pending.
4. Claims 1-13, 34-65 were previously cancelled, but are currently identified as withdrawn.

Rejections Withdrawn

Applicant's arguments, see pages 15-19, filed November 26, 2004, with respect to the rejection under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) with respect to Everhart et al [US 6,060,256] have been fully considered and are persuasive. The rejection of claims 14, 15, 17-24, 26, 29, 31-33 under 35 U.S.C. 102(b) and claims 16, 25, 27, 28, 66 under 35 U.S.C. 103(a) with respect to Everhart et al has been withdrawn.

In particular Everhart et al fails to teach that when the receptors forming the pre-selected patterns are bound to analytes, the resulting diffraction patterns would be distinct from each other.

Claim Objections

5. Claims 1-13, 34-65 are objected to because of the following informalities: the status of the claims are believed to be incorrect, as the claims were cancelled in the response sent December 04, 2003. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 14-33, 66-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. With respect to claims 14, 68, it is unclear from the limitation "wherein each of said pre-selected patterns on said surface.... gives rise to a pre-selected diffraction pattern distinct from any other diffraction pattern when the analyte-specific receptor which forms said pre-selected pattern is bound to the appropriate analyte" whether applicant is referring to all diffraction patterns, including those not on the substrate, or if applicant is only referring to other bound pre-selected patterns, or if applicant intends that when the receptors of a said pre-selected pattern is bound to an analyte, the diffraction pattern formed is distinct from diffraction patterns formed from all other unbound and bound pre-selected patterns on the substrate. Currently, the last interpretation is assumed.

9. The remaining claims are indefinite due to their dependence on an indefinite claim.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 14, 15, 17-19, 66, 20-21, 23-24, 27, 29- 32, 66, 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al [US 5,512,131].

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Kumar et al teach a method comprising providing a surface where a variety of combinations of different stamping patterns, different pattern orientations and different stamping steps may be combined with a variety of pattern shapes and a variety of molecular species to produce a large variety of potential SAMs on a material surface (column 2, lines 3-20), where the SAMs may be comprised of different molecular species (column 3, lines 21-30) that selectively bind to various biological or other chemical species (column 11, lines 64 – column 12, line 9). Kumar et al further teach that the SAMs may be illuminated with coherent electromagnetic radiation, and a diffraction pattern observed, the intensity of the diffraction pattern used to quantitate the amount of immobilized label (column 16, lines 26-30). Kumar et al fail to specifically teach that each pattern gives rise to a pre-selected diffraction pattern distinct from other analyte diffraction pattern when the analyte binds to the receptors of the pre-selected pattern.

Kumar et al, however, do provide an example where different molecular species are used to create a SAM pattern with different regions and diffraction patterns (column 20, lines 5-20, fig. 6).

Therefore it would have been obvious that illumination of the SAMs with different patterns of different molecular species that selectively bind to various biological species would produce different diffraction patterns, allowing for the detection and quantitation of different biological species.

12. With respect to claim 15, Kumar et al teach that a large region of regions may be illuminated and a diffraction pattern observed, the intensity of the diffraction pattern being used to quantitate the amount of immobilized label (column 16, lines 25-30).

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13. With respect to claims 17-19, 66, Kumar et al teach that the intensity of the diffraction pattern reflected from the surface can be compared between initial no diffraction, to intense diffraction, to diffuse reflection (column 19, example 5, fig.1c).
14. With respect to claims 20-21, teach a coherent laser beam for producing diffraction patterns (column 13, lines 49-55), such as a He:Ne laser with a wavelength=632.8 (column 20, example 5).
15. With respect to claims 23-24, the substrate may be partially reflecting when the binding partners are tagged with gold (column 16, lines 20-25), or reflecting when the substrate is gold (column 10, lines 55-67). Analysis is thus made on the basis of reflectants (column 16, lines 24-26).
16. With respect to claim 27, Kumar et al teach that by monitoring the intensity of the image of diffracted light as a function of time, the degree of contamination can be determined (columns 19-20, example 5).
17. With respect to claim 29, the receptors may be antibodies, antigens (column 15, lines 52-60).
18. With respect to claims 30, 68, Kumar et al teach that preferred materials upon which the patterns are located (fig. 1a) include gold, silicon, glass (column 10, lines 55-67).
19. With respect to claim 31, Kumar et al teach a sandwich assay in which a medium containing second binding partner that would bind to the analyte when it binds to functionalities on regions may be provided (column 16, lines 15-19).
20. With respect to claim 32, Kumar et al teach that the standard material can be a metal colloid, specifically gold (column 16, lines 23-24).

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21. With respect to claim 67, the patterns may intersect (column 2, lines 65-67).
22. With respect to claim 69, Kumar et al teach that the material may be polystyrene (column 14, lines 50-61).
23. With respect to claim 70, Kumar et al teach that by monitoring the intensity of the image of diffracted light as a function of time, the degree of contamination can be determined (columns 19-20, example 5).
24. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al [US 5,512,131] in view of Yguerabide et al [US 6,586,193].

Kumar et al teach a method involving illuminating the patterns on a substrate, as discussed above. Kumar et al do not specifically teach illuminating the patterns one at a time.

Yguerabide et al, however, teach the limitation of illuminate the patterns separately (column 98, lines 7-18), in order to avoid cross talk or other similar problems (column 97, lines 60-65).

Therefore, it would have been obvious to illuminate the patterns one at a time, as taught by Yguerabide et al, in the method of Kumar et al, in order to avoid cross talk or other similar problems.

25. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al [US 5,512,131] in view of Sandstrom et al [US 5,494,829].

Kumar et al teach a method of screening for analytes as discussed above. Kumar et al do not teach the step of rinsing and drying the substrate after contacting the substrate with a medium and prior to illumination.

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Sandstrom et al, however, do teach a step of rinsing and drying the substrate after an incubation period. Sandstrom et al further teach that this step is used to separate the unbound material from the reacted film (column 31, lines 20-24). Therefore it would have been obvious to have a rinse and dry the substrate after contacting the surface of the substrate with the medium and prior to illumination, as taught by Sandstrom, in the method of Kumar, in order to separate unbound material from the reacted film.

26. Claims 26, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al [US 5,512,131] in view of Everhart et al [US 6,060,256].

With respect to claim 26, Kumar et al teach a method of screening for analytes as discussed above. Kumar et al do not teach placing the substrate in a cell containing a medium being screened for analytes, said cell having at least one optical window for light to pass therethrough for detecting for analytes in said medium in situ.

Everhart et al, however, teach a method in which the biosensor is placed on the inside surface of a container such as a glass vial, where the biosensor can then be visualized to detect the presence of multiple analytes in a medium using a single test (column 8, lines 33-45). This would allow for determination of microbial contamination (column 8, lines 40-45).

Therefore it would have been obvious in the method of Kumar, to place the biosensor is placed on the inside surface of a container such as a glass vial, where the biosensor can then be visualized to detect the presence of multiple analytes in a medium using a single test, as suggested by Everhart et al, to allow for detection of microbial contamination.

27. With respect to claim 33, Everhart et al teach a method where the medium is selected from the group consisting of blood, serum, plasma and urine (column 6, lines 60-61).

28. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al [US 5,512,131] in view of Bouma et al [US 5,585,242].

Kumar et al teach a method of screening for analytes as discussed above. Kumar et al do not teach that the light illuminating the substrate is directed toward the substrate at an effective angle such that it undergoes total internal reflection from the substrate/medium interface.

Bouma et al, however, teach that use of total internal reflection elements allows performing a homogenous assay (i.e. free of separation and wash steps) for members of specific binding pairs (column 2, lines 65-67).

Therefore it would have been obvious for the light illuminating the substrate to undergo total internal reflection, as suggested by Bouma et al, in the method of Kumar et al, in order to perform a homogenous assay.

Allowable Subject Matter

29. Claim 22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

30. Applicant's arguments with respect to claims 14-33, 66-70, have been considered but are moot in view of the new ground(s) of rejection.

The following argument, however, has been addressed, in order to further clarify the invention being claimed. With respect to applicant's argument that Kumar et al does not teach simultaneously detecting for the presence of two analytes in a medium, it is not entirely clear

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whether the invention being claimed by applicants does necessarily simultaneously detect for the presence of two analytes in a medium, particularly in light of claim 16, which states that illuminating said substrate includes illuminating the patterns one a time. Further clarification would be greatly appreciated.

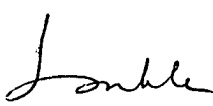
Conclusion

- 31. No claims are allowed.
- 32. Claims 1-13, 34-65 are objected to.
- 33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

- 34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641


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02/07/05